

**PROTOCOL TITLE:**

One Team: Changing the Culture of Youth Sport

**NCT#:** STUDY00000972

**DATE:** 11/13/2019

# Email to Coaches

## INTERVENTION

Dear [stakeholder group],

[League name] is participating in a research study this season called “One Team” which is working to decrease concussion risk in youth sport. You might see study team members at games this season, observing and/or recording the huddles, and they might ask you to talk about pre-game safety huddles and/or report whether or not one took place. The research team might also ask you and your team to be one of the teams that fills out surveys **three** times during the season about your attitudes and beliefs about sport safety. As a “thank you” the study team would bring you and your team snacks while you fill out the surveys each time. After the third time, they will bring you pizza!

Participating in feedback about the huddles and filling out the surveys is voluntary. If you do not want to participate in this or any part of the study, please notify study staff, using their contact information below.

Here is some more information about the study, for your reference:

### ***What is the goal of the One Team study?***

To change the culture of youth sport in order to decrease concussion risk

### ***What is the study trying to change?***

There are two outcomes we are focusing on:

#### 1. Sportsmanship

Encouraging athletes to behave in a sportsman-like manner to decrease illegal and dangerous collisions that have a high rate of concussions (such as targeting or spearing in football or charging an opponent in soccer)

#### 2. Concussion reporting

Increasing the likelihood of athletes reporting concussive symptoms

### ***How will the study make those changes?***

Athletes are familiar with “huddles” on the sports field, and they are a powerful way to pump up the team for competition. Huddles have also been used to talk about safety in medical settings, like before a big surgery. The goal of our research is to understand how pre-game huddles can be used to promote safety in sports.

***What can I do?***

As mentioned above, researchers will be coming to some of your games to observe the huddles and to get feedback about the huddles through brief interviews. They might also ask you to fill out surveys three times throughout the season. Participation in the interviews and surveys is voluntary, but the study team would love to hear what you think about the huddles and how they could be better.

***Who should I contact if I have more questions?***

Feel free to email the study team if you have questions:

Emily Kroshus, ScD MPH Sara Chrisman, MD MPH

[Emily.kroshus@seattlechildrens.org](mailto:Emily.kroshus@seattlechildrens.org) [Sara.Chrisman@seattlechildrens.org](mailto:Sara.Chrisman@seattlechildrens.org)

IRB #: STUDY00000972

**Study Title:** One Team: Changing the Culture of Youth Sport

**Principal Researcher:** Emily Kroshus, ScD, MPH and Sara Chrisman, MD, MPH

**Revision Date:** 11.13.2019 **Protocol Version Date:** 11.13.2019

# Information Sheet for Coaches

**Study Title:** Experiences with the One Team Safety Huddles

**Principal Researchers:**

**Emily Kroshus, ScD, MPH**

**Sara Chrisman, MD, MPH**

Seattle Children's Research Institute & University of Washington, Department of Pediatrics

## 1. Researchers' Statement:

This is an information form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would give your verbal consent to the researchers.

## 2. What you should know about this study:

- This form explains what would happen if you join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your participation in the sports league.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at any time.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later

## 3. What is the goal of this study?

The goal of any research study is to answer questions. The One Team study, through the use of safety huddles, aims to shift the culture of safety in youth sport. Your league decided to participate in the study and was randomized to try out safety huddles. Other leagues will continue to play games as normal. We are doing this research study to answer the following questions: What are the attitudes and beliefs of youth athletes, parents, coaches and referees about sport safety and how are these affected by the One Team huddle intervention?

## 4. Why do I have the option of joining the study?

You have the option to take part in this research study because your league has been selected to participate in pre-game safety huddles.

### **5. How many people will take part in the study?**

We think that about 1,800 people will participate in this study.

### **6. If I agree to join this study, what would I need to do?**

If you decide to take part in this study, you are agreeing to be observed by the research team if you take part in the safety huddle. We might also ask you to participate in an interview and/or survey about the safety huddle or ask you to complete 3 surveys throughout the season. Someone would come to your game or practice with the surveys. There would also be an option to complete them on-line.

If we conduct an interview with you, the interview will be audio-recorded and transcribed so that we can better analyze the information.

### **7. How long would I be in the study?**

If you choose to take part in all study activities, you would be in the study until you complete the interview and/or surveys.

If you join the study, you can decide to stop **at any time for any reason**.

### **8. What are the potential harms or risks if I join this study?**

You might feel uncomfortable answering some questions. You can skip any questions you do not want to answer.

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

### **9. What are the potential benefits if I join this study?**

We do not expect this study to benefit you. We hope to use information we get from this study to benefit other youth athletes.

### **10. What other options do I have?**

You can choose not to participate in this study.

### **11. How would you keep my information confidential?**

If you join the study, we will keep your information confidential as provided by law.

This information may include things like:

- Past or future medical records,

- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday
- This study might potentially include an audio recording of a huddle you led or were a part of. Neither your name nor any other identifying information will be associated with the audio or the transcript. This recording may be used for educational purposes by the study team

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children’s Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,
- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If you and your child’s information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

If the results of the study are published, information that identifies you would not be used.

Your permission to participate is given by participating in a huddle or survey. If you decide that we cannot use or share your information, you cannot participate in this study.

## **12. Would it cost me money to be in the study?**

If you take part in this study, there would be no cost to you and no cost to your insurance company.

Anyone who participates in the interview about their experience with the huddle will receive a \$40 gift card. All other participation will not be compensated.

#### **14. Who do I contact if I have problems, questions or want more information?**

##### **Questions?**

If you think you or your child have been harmed from this study, please call 610-772-6061. For questions about you or your child's rights as a research participant, please contact the Institutional Review Board at (206) 987-7804.

##### **Do I have to take part in this research?**

No. Your participation is voluntary. If you join the study, you can decide to stop at any time for any reason. You and your child will not lose any benefits or be penalized if they choose to leave the study.

If you do NOT want your child to participate in this study, please contact the principal investigator at the email address or phone number listed below.

Emily Kroshus, ScD MPH

[emily.kroshus@seattlechildrens.org](mailto:emily.kroshus@seattlechildrens.org)

[Aim 2-3]



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**Information Sheet (HRP-502D)**

Seattle Children's IRB Approved Effective: 12/11/2019

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IRB #: STUDY00000972

**Study Title:** One Team: Changing the Culture of Youth Sport

**Principal Researcher:** Emily Kroshus, ScD, MPH and Sara Chrisman, MD, MPH

**Revision Date:** 11.13.2019 **Protocol Version Date:** 11.13.2019

# Information Sheet for Parents and Athletes

**Study Title:** Experiences with the One Team Safety Huddles

**Principal Researchers:**

**Emily Kroshus, ScD, MPH**

**Sara Chrisman, MD, MPH**

Seattle Children's Research Institute & University of Washington, Department of Pediatrics

## 1. Researchers' Statement:

**Parents/Guardians:** Your child has the option to take part in a research study. The goal of this form is to give you information about what would happen in the study if your child chooses to take part and to help you decide if you want your child to be in the study.

**Potential Participants 18 years and older:** This is an information form. It provides a summary of the information the research team will discuss with you. If you decide that you would like to take part in this research study, you would give your verbal consent to the researchers.

The word “**you**” in this form may refer to you and/or your child.

## 2. What you should know about this study:

- This form explains what would happen if you and your child join this research study.
- Please read it carefully. Take as much time as you need.
- Please ask the research team questions about anything that is not clear.
- You can ask questions about the study any time.
- If you choose not to be in the study, it will not affect your participation in the sports league.
- If you say 'Yes' now, you can still change your mind later.
- You can quit the study at any time.
- You would not lose benefits or be penalized if you decide not to take part in the study or to quit the study later.

## 3. What is the goal of this study?



The goal of any research study is to answer questions. The One Team study, through the use of safety huddles, aims to shift the culture of safety in youth sport. Your league decided to participate in the study and was randomized to try out safety huddles. Other leagues will continue to play games as normal. We are doing this research study to answer the following questions: What are the attitudes and beliefs of youth athletes, parents, coaches and referees about sport safety and how are these affected by the One Team huddle intervention?

#### **4. Why do I have the option of joining the study?**

You have the option to take part in this research study because your league has been selected to participate in pre-game safety huddles.

#### **5. How many people will take part in the study?**

We think that about 1,800 people will participate in this study.

#### **6. If I agree to join this study, what would I need to do?**

If you decide to take part in this study, you are agreeing to be observed by the research team if you take part in the safety huddle. We might also ask you to participate in an interview about the safety huddle or ask you to complete 3 surveys throughout the season. Someone would come to your game or practice with the surveys. There would also be an option to complete them on- line.

If we ask you for an interview, the interview will be audio-recorded and transcribed so that we can better analyze the information.

#### **7. How long would I be in the study?**

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If you choose to take part in all study activities, you would be in the study until you complete the interview and/or surveys.

If you join the study, you can decide to stop **at any time for any reason**.

#### **8. What are the potential harms or risks if I join this study?**

You might feel uncomfortable answering some questions. You can skip any questions you do not want to answer.

There is a risk that your confidentiality or privacy could be breached. This would mean that someone other than the research team or our collaborators may find out that you were in the research or see your answers or medical information. However, we will take every precaution to make sure that this does not happen.

### **9. What are the potential benefits if I join this study?**

We do not expect this study to benefit you or your child. We hope to use information we get from this study to benefit other youth athletes.

### **10. What other options do I have?**

You can choose not to participate in this study.

### **11. How would you keep my information confidential?**

If you join the study, we will keep your information confidential as provided by law.

You have certain privacy rights with regards to your health information, and only with your permission may we collect, use, or share your health information for this study. The following describes the type of information the study will create, use or share, who may use it or share it, and the purposes for which it may be used or shared.

This information may include things like:

- Past or future medical records,
- Research records, such as surveys, questionnaires, interviews, or self-reports about medical history
- Medical or laboratory records related to this study, and
- Information specific to you like your name, address, or birthday

This study might potentially include an audio recording of a huddle you were a part of. Neither your name nor any other identifying information will be associated with the audio or the transcript. This recording may be used for educational purposes by the study team.

This information may be used by or shared with:

- Researchers (such as doctors and their staff) taking part in this study here and at other centers,
- Research sponsors – this includes any persons or companies working for, with, or owned by the sponsor,
- Review boards (such as Seattle Children's Institutional Review Board), data and safety monitoring boards, and others responsible for watching the conduct of research (such as monitors),
- Governmental agencies like the U.S. Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS), including similar agencies in other countries, and
- Public health authorities to whom we are required by law to report information for the prevention or control of disease, injury, abuse, or disability.

This information may be used or shared to:

- Complete and publish the results of the study described in this form,

- Study the results of this research,
- Check if this study was done correctly, and
- Comply with non-research obligations (if we think you or someone else could be harmed).

You may look at or copy the information that may be used or disclosed. However, for certain types of research studies, some of the research information may not be available to you during the study. This does not affect your right to see what is in your medical (hospital) records.

There is no time limit for the use or sharing of your child's information. Researchers continue to analyze data for many years, and it is not always possible to know when they will be done. If you and your child's information will be banked as part of this study, it may be used in the future for other research. We would not ask for your permission prior to this future research.

Your permission for the use or sharing of your child's information will not expire, but you may cancel it at any time. You can do this by notifying the study team in writing. If you cancel your permission, no new information will be collected about your child, but information that has already been collected may still be used and shared with others.

The use or sharing of your information will follow privacy laws, but these laws only apply to doctors, hospitals, and other health care providers. Some people who receive your health information as part of this study may share it with others without your permission if doing so is permitted by the laws they must follow.

If the results of the study are published, information that identifies you or your child would not be used.

Your permission is documented by participating in a huddle or providing your verbal consent to the researcher. If you decide that we cannot use or share your information, you cannot participate in this study.

## **12. Would it cost me money to be in the study?**

If you take part in this study, there would be no cost to you and no cost to your insurance company.

## **13. Would I be paid if I join this study?**

Anyone who participates in the interview about their experience with the huddle will receive a \$40 gift card. All other participation will not be compensated.

## **14. Who do I contact if I have problems, questions or want more information?**

### **Questions?**

If you think you or your child have been harmed from this study, please call 610-772-6061. For questions about you or your child's rights as a research participant, please contact the Institutional Review Board at (206) 987-7804.

### **Do I have to take part in this research?**

No. Your participation is voluntary. If you join the study, you can decide to stop at any time for any reason. You and your child will not lose any benefits or be penalized if they choose to leave the study.

If you do NOT want your child to participate in this study, please contact the principal investigator at the email address or phone number listed below.

Emily Kroshus, ScD MPH



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